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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,775	08/21/2003	Tamar Tennenbaum	HEALOR-202	6931

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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	PAPER NUMBER
1647	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,775	TENNENBAUM, TAMAR	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *131-144* is/are pending in the application.

4a) Of the above claim(s) *140 and 141* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *131-139 and 142-144* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *131-144* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/24/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 6/23/08 have been fully considered but they are not persuasive.

Claims 1-130 have been cancelled. Claims 131-144 have been newly added.

Election/Restrictions

Newly submitted claims 140-141 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally elected invention was a pharmaceutical composition comprising insulin or insulin in combination with a synergistic agent. These components are present with a pharmaceutically acceptable carrier intended for topical application. (See restriction requirement dated 10/24/06.) Original claims 41, 44, and 102 are reproduced below.

41. A pharmaceutical composition for inducing or accelerating a healing process of a skin wound, the pharmaceutical composition comprising, as an active ingredient, a therapeutically effective amount of insulin and at least one additional agent acting in synergy with said insulin, and a pharmaceutically acceptable carrier being designed for topical application of the pharmaceutical composition.

44. The pharmaceutical composition of claim 41, wherein said at least one additional agent is a PKC-α inhibitor.

102. A pharmaceutical composition for inducing or accelerating a healing process of a skin wound, the pharmaceutical composition comprising, as an active ingredient, a single dose-unit of insulin selected capable of inducing or accelerating a healing process of the skin wound, and a pharmaceutically acceptable carrier being designed for topical application of the pharmaceutical composition.

Claim 140 is directed to a myristoylated peptide in the absence of insulin.

Claim 141 is directed to a myristoylated peptide in the absence of insulin or such a pharmaceutically acceptable carrier.

These are patentably distinct compositions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 140-141 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claims 133 and 144 are objected to because of the following informalities: The claims each contain two periods (".") at the end of the claim. Appropriate correction is required.

Inventorship

The inventorship of the instant application is Tamar Tennenbaum. Applicant's previously submitted petition under 37 CRF 1.48(a) to add back the deleted inventors Sampson, Kuroki, Alt, and Shen was deficient. Applicant's present response does not correct these deficiencies.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 131, 133-137, 139, and 142-144 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 249, 254, 273, 277-278, 283-288, and 296-298 of copending Application No. 11/332,774. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to pharmaceutical compositions for wound healing comprising an agent, such as the N-myristoylated PKCα inhibitor of SEQ ID NO: 1, and insulin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant is reminded to maintain a clear demarcation between the claims of co-pending applications. Applicant is requested to advise the examiner of any other co-pending applications with claims directed to similar subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 132, 138, 139, and 142-144 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 132, 138, 139, 142, 143, and 144 are not original claims.

Applicant has pointed to basis in Example 23 and Table 1. This is not agreed with.

Claim 132 is directed to a composition comprising insulin and a PKCα. There does not appear to be any contemplation of these compositions.

Claim 138 is directed to an article of manufacture comprising formulations of claim 137 applied on a solid support. There does not appear to be any contemplation of these articles of manufacture.

Claims 139, 143, and 144 are directed to compositions comprising buffers. There does not appear to be any contemplation of buffers as preferred subgenus of pharmaceutically acceptable carriers. Claim 142 (as it depends on non-elected claim 141) is considered to embrace new matter for the same reason.

The specification does not appear to disclose generic compositions but rather appears to disclose only pharmaceutical compositions containing a pharmaceutically acceptable carrier and for the intended use of inducing or accelerating a healing process of a skin wound but not other uses. As such, claims 139 and 143 are considered to embrace new matter.

Claim 144 is considered to be new matter because the pharmaceutical compositions are not limited to those suitable for topical administration or skin wounds. These other pharmaceutical compositions were not contemplated.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 133-138, 142, and 144 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 133 recites "pharmaceutical composition a single dose-unit of insulin." It is unclear what is being claimed. It appears that a word or phrase is missing. In addition, the amount of insulin required is unclear. The dose would be dependent upon the subject being treated and the nature of the condition being treated. The claim does not specify who the patient is (animal, human) or the size or severity of the skin wound.

Claim 134 is indefinite and does not clearly further limit the subject matter of claim 133. The recitation "for topical administration" is an intended use and does not clearly require any components in addition to those recited in claim 133.

Claim 142 is indefinite for depending upon a non-elected claim.

Claim 144 is indefinite for reciting "when applied to a patient in need thereof." It is unclear what this limitation is intended to embrace. If applicant intended to limit the claims to those pharmaceutical compositions suitable for topical administration, this is not clear from this claim language. An intended use is not a clear requirement for any particular component.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 133-138 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al. (U.S. Patent No. 5,770,228).

Edwards et al. discloses and claims a pharmaceutical composition comprising PDGF-BB and insulin in a cellulose gel for use in wound healing. See at least abstract and claims. The patent does not specify whether the insulin is from natural or recombinant sources and is considered to include insulin from any source just as the PDGF may be from natural or recombinant sources (see column 2, lines 55-60). The instant specification makes clear that insulin from both sources would have been well known at the time of the invention.

In the absence of a more specific definition, the cellulose gel is deemed to meet the limitation of a solid support as recited in claim 138.

Applicant is reminded that intended use and functional language are given no patentable weight in a product claim. Absent evidence to the contrary, the amount of insulin in the cellulose gel would meet the limitation for single dose-unit sufficient to induce or accelerate a healing process of the skin wound in a subject as Edwards et al. is directed to wound healing.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa